

REMARKS/ARGUMENTS

Claims 1-44 have been canceled. Claims 45-58 remain in this application. Claims 59-70 have been added. Claims 45-70 are currently under consideration.

Applicants thank Examiner Di Nola-Baron for the very helpful personal interview on May 7, 2003 and have taken that discussion into account in amending the claims.

Newly added claims 59-70 are fully supported in the specification.

The sole ground of rejection in the Office Action dated February 14, 2003 – an obviousness rejection over USP 5,521,089 (“Ishiguro”) – is respectfully traversed.

Ishiguro does not suggest or disclose the presently claimed invention

Contrary to the allegation of the Examiner, Ishiguro does not suggest or disclose the processes and compositions recited in the present claims. Ishiguro discloses methods of making microcapsules, in each of which a coating of yeast material from a single yeast particle encapsulates a hydrophobic *liquid*. See, *e.g.*, the title of the reference (“Process for treating yeast ... to produce microcapsules enclosing hydrophobic liquids”) and the Summary of the Invention at col. 2, lines 45-48 (“[T]he present invention provides a process for producing highly practical microcapsules comprising yeast cells in which a hydrophobic liquid is enclosed ...”). A drawing comparing features of the coating of the present invention with the microcapsules of Ishiguro is attached.

In the personal interview on May 7, 2003, the Examiner pointed to col. 5, lines 33-37 of the reference, which states that “Dyes, perfumes, pharmacologically active substance, food material, feed materials or the like are dissolved or *dispersed* in the hydrophobic liquids ... and then the liquids are encapsulated.” The Examiner alleged that the materials *dispersed* in the hydrophobic liquid are, in fact, *solid* materials, albeit present in a liquid context. Applicants disagree with this interpretation of the reference, and maintain that a dispersal is qualitatively different from a solid material. Nevertheless, in an effort to expedite prosecution, claims 45, 46, 52 and 53 have been amended to recite “coating the surface of a solid material,” or “the coating on the surface of the solid material.” The amendments merely clarify the claims, and do not narrow their scope.

Coated materials and coating agents produced by the instant processes exhibit unexpectedly desirable properties. For example, the coating agent can be used as an excellent enteric coating agent that is capable of encapsulating greater amounts of a substance without compromising the function of protecting the encapsulated substance; the process of making the coating agent allows the time at which dissolution begins to be controlled; the coatings have a non-sticky finish, and they exhibit an extremely low permeability to oxygen or other gasses and to moisture. See, *e.g.*, the specification at page 5, lines 7-12; page 12, lines 11-17; and page 13, line 16 to page 14, line 1.

Claims which recite treatment with an acidic solution

Claims 45- 51, and new claims 59-63, which recite a “cell residue of yeast which has been treated with enzymes and subsequently *acidic solution*” are still further distinguished from Ishiguro.

In the personal interview on May 7, 2003, the Examiner pointed to col. 4, lines 15-24 of the reference, which states that “optimum conditions for many enzymes are usually pH 4-9” and that “termination of the enzyme reaction can be carried out by ... adjustment of pH.” The Examiner interpreted this section to mean that, following treatment of the yeast with an enzyme at basic pH, the reaction can be terminated by adding acid to adjust the pH. This process, she alleged, is the same as the recitation in claim 45 that the yeast “has been treated with enzymes and subsequently acidic solution.”

However, the Examiner’s interpretation is unwarranted. Ishikuro discloses a variety of methods that can be used other than the addition of an acid to terminate its enzymatic reactions. For example, the reference discloses that some enzymes function at an acid pH (4-7), in which case the reaction could presumably be terminated by adding a *basic* solution. Furthermore, the reference discloses that the termination can be carried out by “separating the yeast cell from the enzyme by centrifugation, washing or the like, by deactivating the agent by heating ... or using a deactivator, and by other suitable methods” (col. 4, lines 22-26). The reference provides no motivation to select any particular treatment (such as treatment with an acid) from this long list of possibilities.

The presence of Examples is not required in a U.S. patent. Nevertheless, one may look to Examples for guidance in interpreting claims. In the present case, if one looks for

guidance in the Examples of the Ishiguro patent, one is not lead to adding an acidic solution to terminate an enzymatic reaction. Not one of the Examples that uses an enzymatic treatment (Examples 3, 4 and 5) terminates the enzymatic reaction in this manner. Rather, in each of Examples 3-5, the enzymatic reaction (with either Zymolyase or Kitalase) is terminated by treating with base (pH 10).

Therefore, Ishiguro does not suggest to one of skill in the art to treat yeast with enzymes and subsequently acidic solution, as is recited in claims 45- 51 and new claims 59-63.

Plasticizers

The Examiner's allegation that Ishiguro discloses the recitation in claims 48 and 55 that the coating agent further comprises a "plasticizer" is unwarranted. The Examiner alleges that, because the microcapsules of Ishiguro may enclose hydrophobic liquids, such as oils, the reference "contemplates plasticizers." This is incorrect; the reference does not suggest or disclose using plasticizers as part of the coating agent, itself, as is recited in claims 48 and 55. See also the specification at page 13, lines 3-6.

New claims

Newly added claims 59-70 are further distinguished from Ishiguro, for at least the following reasons:

1. New claims 59 and 65 (and claims dependent from them) recite that the yeast has been treated with *an enzyme that is specific for a yeast cell wall substance and an additional enzyme*. This recitation is supported in the specification, *e.g.*, at page 10, lines 9-17; among the types of additional enzymes listed are, *e.g.*, nucleases, esterases or lipases. Ishiguro does not suggest or disclose a method comprising treating yeast with an additional enzyme other than one specific for a yeast cell wall substance. (The use of cell wall dissolving enzymes is disclosed in Ishiguro at, *e.g.*, col. 3, line 47 to col. 4, line 14.)
2. New claims 62 and 68 recite that the yeast has been further *pre-treated to physically rupture the cell walls*. This recitation is supported in the specification, *e.g.*, at page 10, lines 20-24 ("To speed up or the like, the enzyme treatment, pretreatment for physically

rupturing the cell walls with a high pressure homogenizer or the like may be carried out before the enzyme treatment of the yeast.”). Ishiguro does not suggest or disclose a treatment that ruptures the cell walls prior to treatment with an enzyme. If anything, the reference teaches that its particles “can be efficiently ruptured,” at a *later* stage, after formation of the microcapsules, “when the enclosed substance is to be released” (col. 2, lines 38-40).

3. New claims 63 and 69 recite a process comprising providing a coating agent comprising yeast cell wall fractions ... consisting of yeast which has been *solely* treated with enzymes and subsequently acidic solution, and water to remove internal soluble cell constituents (claim 63); or which has been *solely* treated with enzymes and water to remove internal soluble cell constituents (claim 69). New claims 64 and 70 recite a process *consisting essentially of* the steps recited in those claims. Claims 63, 64, 69 and 70 exclude steps of enclosing a hydrophobic liquid within the coating material.

By contrast, the Ishiguro patent is directed to a process for generating microcapsules that enclose hydrophobic liquids. See, *e.g.*, the title of the reference (“Process for treating yeast ... to produce microcapsules enclosing hydrophobic liquids”) and the Summary of the Invention at col. 2, lines 45-48 (“[T]he present invention provides a process for producing highly practical microcapsules comprising yeast cells in which a hydrophobic liquid is enclosed ...”). Ishiguro clearly does not suggest or disclose a process in which a hydrophobic liquid is absent from a coating material.

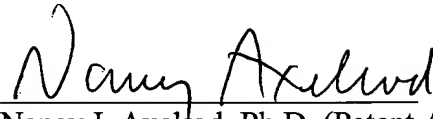
For at least the above arguments, the Ishiguro reference does not render obvious the claimed invention; thus, the rejection should be withdrawn.

In view of the preceding amendments and arguments, it is believed that the application is in condition for allowance, which action is respectfully requested.

Should any additional fee be deemed due, please charge such fee to our Deposit Account No. 22-0261, referencing docket number 38644-175519 (formerly 37833-20011.10) and advise us accordingly. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

A handwritten signature in cursive script, reading "Nancy Axelrod".

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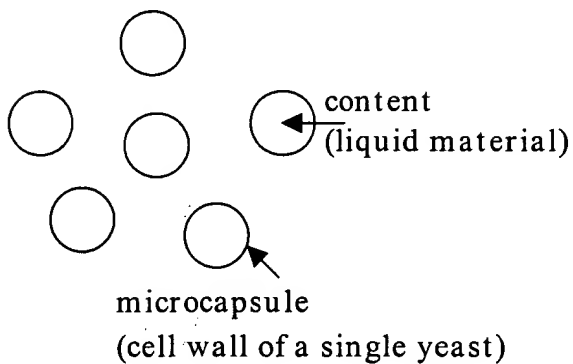
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**AN ILLUSTRATION EXPLAINING THE DIFFERENCE BETWEEN
ISHIGURO ET AL. AND THE PRESENT INVENTION**

ISHIGURO ET AL.



THE PRESENT INVENTION

